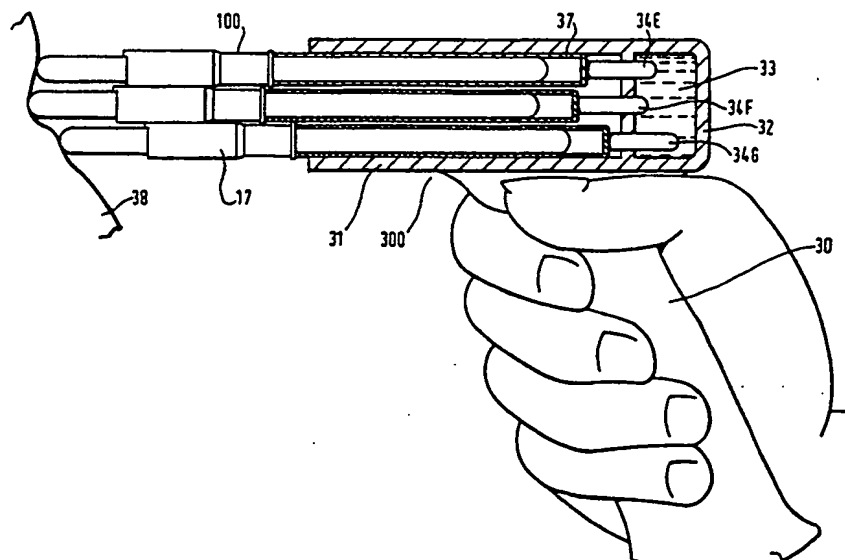


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/30		A2	(11) International Publication Number: WO 98/41250
		(43) International Publication Date: 24 September 1998 (24.09.98)	
(21) International Application Number: PCT/GB98/00716 (22) International Filing Date: 10 March 1998 (10.03.98) (30) Priority Data: 9705292.2 14 March 1997 (14.03.97) GB (71) Applicant (for all designated States except US): WESTON MEDICAL LIMITED [GB/GB]; 2a Hales Barn Workshops, New Street, Stradbroke, Eye, Suffolk IP21 5NG (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): WESTON, Terence, Edward [GB/GB]; Thornlea, Pixey Green, Stradbroke, Eye, Suffolk IP21 5JG (GB). NUSSEY, Matthew, Simon [GB/GB]; 723 Worrall Road, Worrall, Sheffield S30 3AU (GB). (74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>	

(54) Title: NEEDLELESS INJECTOR AND HOLDER THEREFOR



(57) Abstract

A single-use, needleless injector, comprises a capsule which contains a substance to be injected and has an outlet orifice at the distal end thereof. A power unit which has a pre-loaded power source is assembled to the proximal end of the capsule. When the power source is released it causes the said substance to be expelled from the outlet orifice of the capsule. A sleeve is located on the exterior of the injector and is slidable in a direction towards the distal end of the capsule to cause the power source to be released. A holder is provided for holding and operating at least such injector. The holder comprised a housing and a respective support member for the or each injector, mounted in the housing and arranged to receive the proximal portion of the injector and engage the sleeve thereof.

NEEDLELESS INJECTOR AND HOLDER THEREFOR

Needleless injectors are available as alternatives to conventional hypodermic syringes for delivering medicaments through the skin. Usually a high pressure piston pump is employed to force the injectate through a small orifice with sufficient force to pierce the skin. Such devices have been known for more than sixty years, and whilst they promised freedom from the pain of injection and overcame the problems of disposing of contaminated needles, inconvenient operation and sterilisation procedures and poor ergonomic design have meant that they have not enjoyed commercial success.

For many years, multidose injectors for giving sequential injections of one medicament were preferred for large vaccination programmes, because they offered the lowest cost per dose. However, in the 1980's it was found that disease could be spread from one patient to another if the nozzle contacted the skin. Various ideas were tried, such as using disposable nozzles, but the overall inconvenience of this and other characteristics of the apparatus prevented widespread acceptance. More recently, single dose pre-filled injectors having a built-in power source have been developed, and these offer freedom from cross contamination and, in the case of devices developed by the present inventor, extremely user-friendly operation. Such devices can be made for low cost, and have potential for use in mass immunisation programmes.

However, there is a growing requirement for more than one vaccine to be given at one time, but at present there is no known apparatus capable of simultaneous multiple injections. In principle several single dose injectors, each prefilled with a

receive the proximal portion of the injector and engage the sleeve thereof.

In a preferred embodiment, a liquid drug or other medicament or vaccine is contained within a capsule, which capsule has an outlet or injection orifice and a free piston in contact with the injectate. A sealing cap protects the orifice and injectate from contamination. The capsule is assembled to a pre-loaded power source, preferably a compressed gas, or compression spring, for example a helical coil spring, which biases a ram against a latch. A trigger mechanism is provided comprising a sliding sleeve which cooperates with a latch in response to the user pressing the injection orifice onto the skin. The latch is released when the sliding sleeve is moved towards the skin, allowing the ram to accelerate to a high velocity and strike the free piston in the drug capsule. This causes a high skin-piercing force in the first part of the jet of liquid, and the remaining drug is deposited through the hole thus removed, or alternatively, the jet may be fired through the cap. Thus a single use single dose needleless injector is provided, which may be operated to deliver a single dose by holding the trigger sleeve in the hand and pressing the nozzle of the injector. This embodiment is a rudimentary injector and the ergonomics may be imported to suit certain applications by placing the injector into a plastic holder.

However, for simultaneous multiple injections, a plurality of injectors must be assembled together, and this preferred embodiment includes a suitable holder, which preferably comprises a hydraulic chamber into which a number of small pistons are located. The pistons are free to move in and out of the chamber and slide within seals to prevent loss of hydraulic fluid. The outer ends of the pistons are formed as support tubes into which injectors may be inserted. The open ends of the tubes engage the trigger sleeve of the injectors. When the discharge orifices of the multiple

which a resilient seal 12 is located. A cross-hole 13 in ram 10 contains a sliding latch 14 having a conical tip 21, which is biased by a spring 15 to engage with a hole 16 in the wall of the gas cartridge 7. The capsule 1 is retained onto the gas cartridge 7 by lugs 8 engaging with holes 9 in the capsule 1. A triggering sleeve 17, having a ramp 18, prevents the latch 14 from falling out of the cross-hole 13. The cartridge 7 is filled with compressed permanent gas 28 which biases the ram 10 in the direction of arrow A, but the engagement of the latch 14 in the hole 16 prevents movement of the ram 10. Prior to assembly to the drug capsule, the gas cartridge 7 is filled by extending the ram 10 so that a filling hole 20 is uncovered. Pressurised gas is then introduced through the hole 20, and the ram is pushed back to further compress the gas until the latch 14 engages with hole 9 in capsule 1. The assembly of the filled drug capsule and the gas power unit comprises the injector 100.

To operate the injector, the cap 4 is removed and the injection orifice 5 is placed on the subject's skin. The injector is pressed onto the skin by acting on the trigger sleeve 17, which causes the trigger sleeve 17 to move relative to the gas cartridge 7, and the ramp 18 therefore pushes the latch 14 into the cross-hole 13 of the ram 10. When the edge of the conical tip 21 passes through the hole 16, the force of the ram 10 in the direction of arrow A causes the latch 14 to snap completely into the cross-hole 13 in ram 10, so releasing the ram 10. The ram 10 accelerates rapidly to hit the piston 2, causing a very high initial pressure in the drug 3, and thereafter urges the piston 2 with a lower force to discharge the remainder of the drug 3 from the capsule 1. Preferably, there is a gap X between the ram 10 and piston 2. In the less preferred form, where there is no gap between the ram 10 and the piston 2 these two items can be integral with one another). This is to allow momentum to

maybe assembled into a simple frame (not shown). The holder 300 may be fitted with a means for ejecting the frame containing the injectors.

Thus, the multidose injector described provides a simple means of administering a number of different vaccines or other drugs simultaneously. The power is already provided in each injector, so that each injector may be precisely configured as regards dose, viscosity, and depth of penetration. For example the multidose injection could consist of three subcutaneous injections and one intradermal injection. The holder has no power requirements, and serves to control the placement conditions of the injectors on the skin so that optimum performance is realised.

7. An injector according to any preceding claim, comprising a piston arranged to expel said substrate through the outlet orifice, and a ram arranged, in use, to move the piston to cause that expulsion.

8. An injector according to claim 7 wherein, prior to use, there is a gap between the ram and the piston.

9. An injector according to claim 7, wherein the ram and piston are integral with one another.

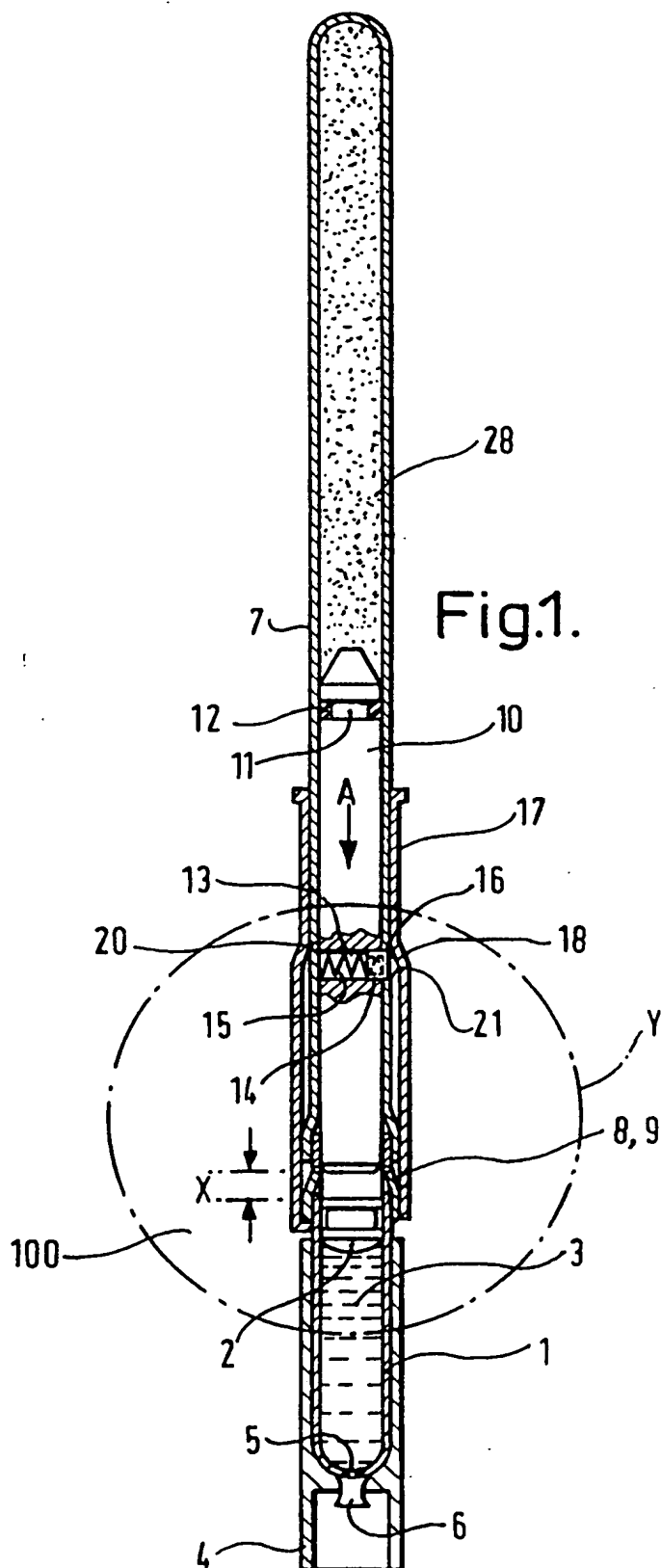
10. An injector according to claim 7, 8 or 9, comprising a latch which, prior to use, prevents movement of the ram, the latch being movable by sliding of the piston towards the distal end of the capsule into a position in which the latch retracts into a cross-hole in the ram.

11. A holder for holding and operating at least one injector according to any preceding claim, which comprises a housing, and a respective support member, for the or each injector, mounted in the housing and arranged to receive the proximal portion of the injector and engage the sleeve thereof.

12. A holder according to claim 11, which comprises a plurality of support members.

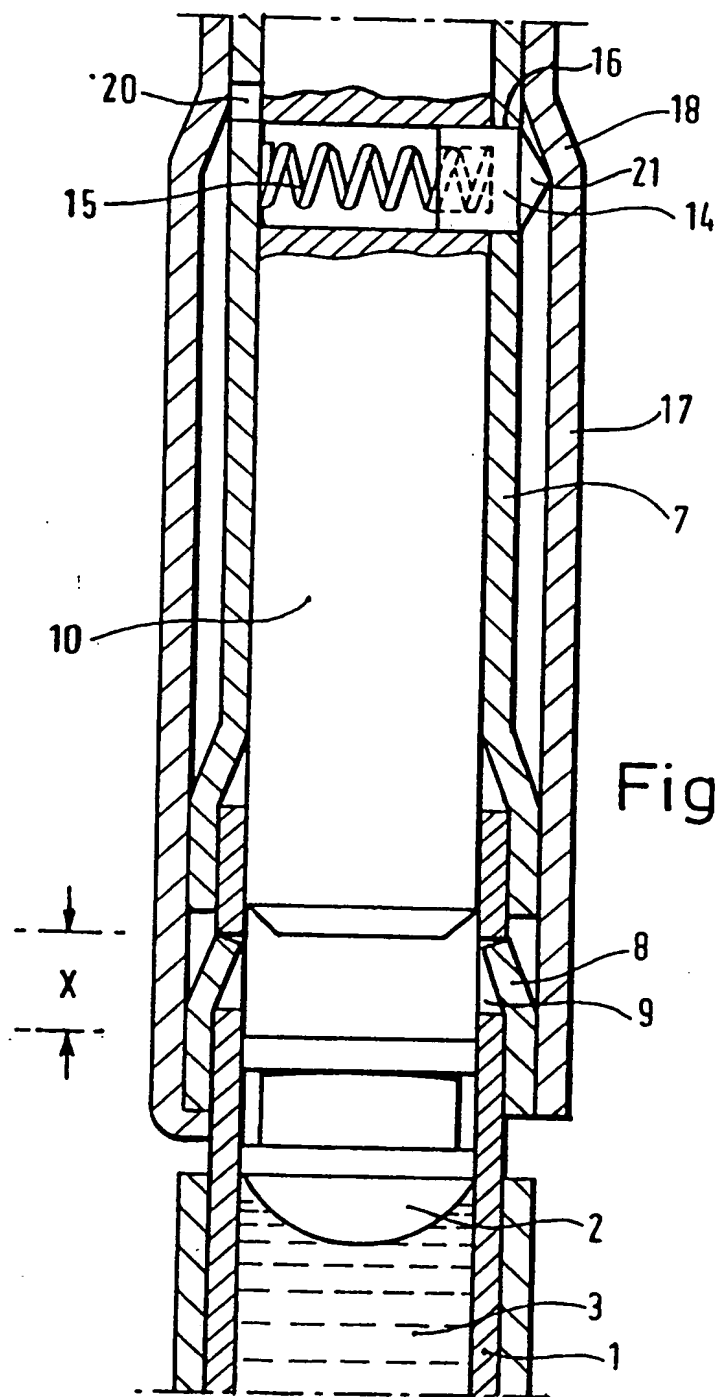
13. A holder according to claim 11 or 12, wherein the holder has a chamber filled

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SUBSTITUTE SHEET (RULE 26)

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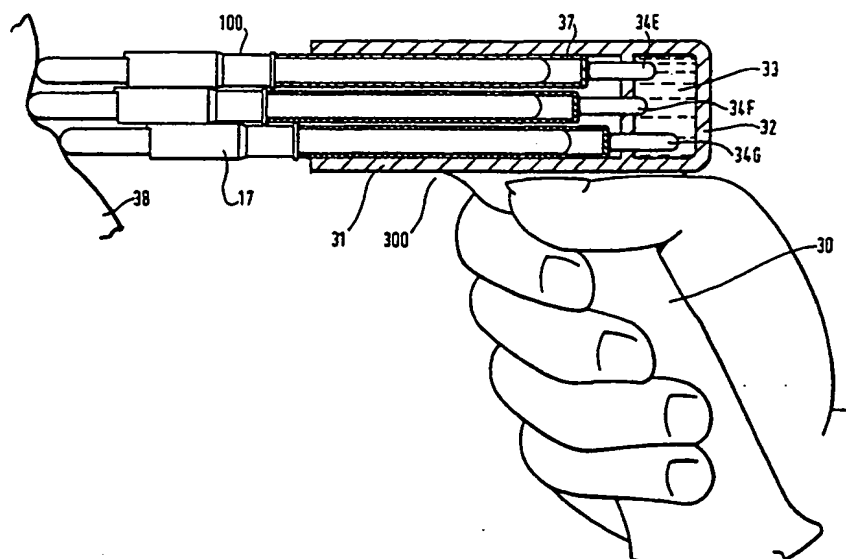




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 24 September 1998 (24.09.98)
(21) International Application Number: PCT/GB98/00716 (22) International Filing Date: 10 March 1998 (10.03.98) (30) Priority Data: 9705292.2 14 March 1997 (14.03.97) GB (71) Applicant (for all designated States except US): WESTON MEDICAL LIMITED [GB/GB]; 2a Hales Barn Workshops, New Street, Stradbroke, Eye, Suffolk IP21 5NG (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): WESTON, Terence, Edward [GB/GB]; Thornlea, Pixey Green, Stradbroke, Eye, Suffolk IP21 5JG (GB). NUSSEY, Matthew, Simon [GB/GB]; 723 Worrall Road, Worrall, Sheffield S30 3AU (GB). (74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> (88) Date of publication of the international search report: 10 December 1998 (10.12.98)	

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INTERNATIONAL SEARCH REPORT

Int'l. Application No.

PCT/GB 98/00716

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 28202 A (WESTON MEDICA LIMITED) 19 September 1996 see page 1, line 1 - line 3 see page 6, line 13 - line 17 see page 7, line 26 - page 8, line 2; figures 1,3	1-3,7,8
A	---	10,11
X	EP 0 406 778 A (NAGY) 9 January 1991 see the whole document	1,3,7
A	---	
A	US 5 190 523 A (LINDMAYER) 2 March 1993 see column 1, line 20 - line 22	4
A	---	
A	GB 691 966 A (DEHN) 27 May 1953 see page 2, line 76 - line 77; figure 3	5

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

5 October 1998

Date of mailing of the international search report

09.10.98

Name and mailing address of the ISA

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Authorized officer

Sedy, R

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/00716

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/00716

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